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USDA FOR FSIS/RAYMOND
USDA FOR FAS OA/YOST, OCRA/ALEXANDER, OSTA/BRANT AND SHNITZLER
COMMERCE FOR ITA/HIJIKATA AND CINO
STATE PASS USTR CHINA OFFICE/TIM WINELAND
STATE PASS OMB/INT'L AFFAIRS
STATE PASS HOMELAND SECURITY COUNCIL
STATE PASS IMPORT SAFETY WORKING GROUP

E.O. 12958: N/A
TAGS: TBIO EAGR ETRD ECON PREL HHS CH
SUBJECT: U.S. FDA COMMISSIONER MEETS WITH CHINESE COUNTERARTS IN SHANGHAI, OCTOBER 10-14, 2007.

REF:A) State 140228
 B) State 86437
 C) Beijing 6265

¶1. (SBU) Summary: U.S. Food and Drug Administration (FDA) Commissioner and Deputy Commissioner traveled to Shanghai October 10-14 to deliver one of the keynote speeches at the Fifth Annual Sino-U.S Symposium on Medicine in the Twenty-First Century and to participate in the centennial anniversary celebration of Jiaotong University's Ruijin Hospital. The delegation also held meetings with State Food and Drug Administration (SFDA) Commissioner Shao Mingli and Vice Commissioner Qu Shuhui, General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) Vice Minister Wei Chuanzhong; and Ministry of Health (MOH) Minister Chen Zhu regarding the two Memoranda of Agreement (MOA) on food and feed safety and on drug and medical product safety. Both SFDA and AQSIQ committed to sending their respective technical teams to Washington this month to continue these MOA discussions face-to-face. Both the U.S. and Chinese officials reaffirmed their commitment to working on the agreements and emphasized the importance their governments place on the safety of food, feed, drug and medical products for the citizens of both countries. The Shanghai visit enabled the FDA Commissioner to engage municipal-level FDA and CIQ (Entry-Exit Inspection and Quarantine Bureau) officials facilitating opportunities for exchanges on procedures and process at these levels and offered them a glimpse of laboratories and port inspection facilities. End Summary.

¶2. (U) Department of Health and Human Services (HHS) Food and Drug Administration (FDA) Commissioner Dr. Andrew von Eschenbach, and FDA Deputy Commissioner Dr. Murray Lumpkin traveled to Shanghai October 10-14 to meet with each of the three Chinese agencies or Ministries responsible for the on-going MOA negotiations on food/feed and drug/ medical product safety.

Shanghai FDA Meetings and Site Visits

¶3. (U) Visiting the Shanghai Food and Drug Administration (SHFDA) and its Institute for Food and Drug Control (SIFDC), Commissioner von Eschenbach learned about the responsibilities and functions of this municipal-level FDA office and its relationships with the national-level SFDA. Introducing the SHFDA as the largest of the 31 provincial and municipal-level FDA, Director-General Dr. Wang Longxing provided an overview on its structure, described the SHFDA responsibilities, and outlined the process and testing methodologies used in the regulation and control of food and drug producers and manufacturers in the Shanghai area. SIFDC Director Dr. Wang Linda outlined the systems used for food and drug supervision and administration, focusing on the testing capabilities and procedures used as well as the Institute's research and development activities. Commissioner von Eschenbach and his delegation toured several laboratories in the Institute.

¶4. (SBU) In a meeting on the drug/medical devices MOA, Vice Commissioner Madam Qu Shuhui, the Chinese side's lead negotiator, expressed appreciation for Commissioner von Eschenbach's visit to Shanghai and acknowledged that since their June 15 phone call (Ref B) there had been three rounds of discussions and two rounds of document exchanges leading to this meeting. She reaffirmed SFDA's commitment and in recognition of the pressures and challenges of globalization, to work collaboratively with the United States FDA. Madam Qu noted increased communications and collaboration between the two agencies illustrated the importance of the agreement. U.S. and Chinese sides expressed mutual appreciation for the earlier joint efforts of the technical teams to achieve agreement on the broad principles of the MOA and to help realize their differences and conflicts yet to be resolved.

¶5. (SBU) Commissioner von Eschenbach emphasized his desire to see

the two agencies build stronger and closer collaborative relationships that would facilitate addressing a variety of challenges. He noted that working together may allow more opportunities to evolve, such as developing mechanisms to share drug and medical product information and to build capacities that would focus quality improvements on prevention throughout a drug or medical product's lifecycle rather than on inspections at the end-stage. Dr. von Eschenbach reiterated FDA's invitation for the SFDA to travel to Washington soon to have further face-to-face discussions on the MOA specifically responding to the second-version sent to the Chinese on September 28. SFDA replied that they would indeed travel to DC the week of October 22 and would provide their written comments on the second-version of the MOA o/a October 17. Both sides also noted that the expected signing of the MOA at SED III will establish a strong foundation for on-going relationships between their agencies to continue to evolve and would protect and promote the health of their own citizens, further making drug and medical products safer for the rest of the world.

Meeting with Health Minister Chen Zhu

¶6. (SBU) (SBU) Commissioner von Eschenbach in his official bilateral meeting with Health Minister Dr. Chen Zhu said he observed from the morning's presentations that both sides shared similar visions to use science and technical knowledge to address global problems. HHS and the MOH already collaborate on many health issues. He congratulated the Minister on his being recently being named a member of the Institute of Medicine and the National Academy of Sciences. The Commissioner also noted that, through these collaborations in health, both of them were responsible to manage the increasing expectations to bring new solutions and safe and effective interventions to their citizens as quickly as possible. These expectations would be facilitated through increased information exchange and closer cooperation between their agencies.

¶7. (SBU) Minister Chen said he was looking forward to December's Strategic Economic Dialogue (SED) in Beijing. He also highlighted the beneficial role of the existing MOU's (on HIV/AIDS and on emerging infectious diseases) between his Ministry and HHS. The

Chinese government pays great ttention to food safety, he eplained, and throughout history always saved the best products (i.e., highest quality) for export, sometimes to the exclusion of the Chinese people. However, even though less than one percent of all food exports had problems, those products need attention; the volume of trade means that the impact of this small percentage could still be significant. [Comment: Interestingly in most other interactions with the Chinese, this figure is presented to mean that over 99 percent of food exports are compliant, meaning they pass Chinese standards for export. This time, the Minister's comment is focused on the small percent that does not pass quality inspection standards. End comment.] Minister Chen recounted the Ministry's many roles in food safety, highlighting its growing engagements with international and multilateral coordination (e.g., with WHO, FAO, and the Codex Alimentaris).

¶8. (SBU) Minister Chen referenced the new leading group on food and product quality led by Vice Premier Wu Yi. China's priority task was to enact new regulations and laws so that the legal environment for food/product safety would be complete. There also needed to be further clarity about the responsibilities among the various Chinese government agencies charged with food and product safety. At a State Council meeting, Chen said that Premier Wen Jiabao had stated clearly that offenders should be punished. Within the Ministry of Health, Chen said he had four priorities with respect to food safety: (1) intensify market rectification; (2) strengthen the supervision/examination system; (3) strengthen risk assessment and reporting and precautionary (or prevention)systems; and (4) establish better standards for food safety.

¶9. (SBU) Minister Chen further indicated his desire to work more closely with and to learn from the FDA in the areas of risk evaluation, risk management and risk assessment. He expressed appreciation for FDA's alert about shipments of contaminated U.S. peanut butter to China. He praised the FDA's transparent approach and commitment to protecting consumers. Echoing comments that each had made in their morning speeches at the Symposium, the two officials noted and agreed that another area for future collaboration (beyond the current food and drug safety issues) was in the research and development of new drugs and conducting clinical trials. Minister Chen also welcomed additional U.S. efforts on capacity building. He also noted that the Chinese media could play a positive role in publicizing food safety problems.

Lunch with AQSIQ Vice Minister Wei Chuanzhong

¶10. (SBU) In the lunch meeting, AQSIQ Vice Minister Wei Chuanzhong acknowledged that he and Commissioner were old friends through correspondence and that the recent discussions between their technical teams was similarly bringing their agencies closer through ongoing dialogues, information sharing, improved understanding and mutual benefits. VM Wei continued by expressing appreciation for the practical and sincere attitudes of the FDA in the food and feed safety discussions where consensus on the main points had already been reached. Promising to provide written feedback next week, VM Wei pledged to try and convince the technical teams to travel to Washington the last week of October. The Vice Minister also indicated that AQSIQ would bring with them on that trip the next batch of information (further data on 15-20 different farm-raising firms) to clear Chinese aquaculture firms from the current detention order. Commissioner von Eschenbach responded by expressing appreciation for the AQSIQ commitment in working towards their common goals of assuring that products are of highest quality and that the MOA, once signed, will serve as a strong foundation upon which both sides can build capacities, address challenges, and learn from each other.

Visit to Shanghai Port

¶11. (U) A visit the Weigaoqiao Entry-Exit Inspection and Quarantine bureau (CIQ) facility offered a glimpse of testing procedures for food safety, demonstrated using a recent arrival of chicken legs.

During this tour, the Commissioner indicated to CIQ hosts Shanghai CIQ Deputy Director-General Xu Chaoje, and Weigaoqiao CIQ Director Dong Chao that the receiving and laboratory inspection facilities as well as the container terminals compared favorably to the Commissioner's recent visits to similar facilities in the United States [Comment: CIQ hosts indicated that Shanghai is the largest port in China, and that last year the Weigaoqiao facilities processed 28,800 ships, over 110 million tons or 21 percent of Shanghai's volume.]

Commissioner's Keynote Speech

¶12. (U) Commissioner von Eschenbach's and Health Minister Chen's keynote speeches contained forward-looking acknowledgements of the rapid bio-medical developments occurring; acknowledgements of the epidemiological shifts in the types of diseases being faced today (fewer communicable and more chronic); and positive assessments of the valuable contributions arising from Sino-U.S. scientific exchanges. Both leaders noted their agencies' efforts to move toward early detection and prevention intervention of diseases. Minister Chen highlighted China's efforts to deliver, and health care for the rural population in the medium and long-term. Advances in science and technology serve as change-agents to facilitate

delivery methodologies and knowledge. The Commissioner's talk similarly acknowledged the rapid changes of science and technology but emphasized a need for both of our countries to focus on the ties that bind us together, uniting the people of the world to fight the common enemy of disease using new interventions and therapeutic agents as well as sharing information. Both speakers referenced how health care is changing and how it needs to incorporate the "four P's" (personalization, predictability; pre-emptive or prevention-focused; participation) to be more effective.

Comment

¶13. (SBU) Commissioner von Eschenbach engaged Minister Chen on several occasions, and the two spoke easily together in English and as scientific colleagues with a high degree of mutual respect and friendliness readily apparent. Their dialogues covered a wide-range of topics including the Minister's research in leukemia and the differences in his responsibilities from a hospital-based (Ruijin Hospital) researcher to now serving as the new Minister of Health. Minister Chen even introduced the Commissioner to his parents during the Symposium dinner banquet as the culmination of his story about his decisions to become a doctor and relating experiences of his early career during and immediately after the Cultural Revolution. Highlighting the difference between these informal interactions and the other formal meetings, Minister Chen before their formal bilateral meeting quietly and apologetically said to Commissioner von Eschenbach in English that, since this was a government meeting, he would have to speak in Chinese.

¶14. (SBU) The Commissioner's interactions with SFDA Commissioner Shao Mingli were characterized by a high-level of mutual friendliness and respect that had clearly developed over the past year since the FDA centennial celebration which Shao attended. Noting that he was but the second SFDA Commissioner (compared to Dr. von Eschenbach being the 20th FDA Commissioner) Commissioner Shao indicated he hoped that he could learn from their relationship and that SFDA could benefit more from the budding collaboration and cooperation evolving between their agencies. Madam Qu, as she had done in July in Washington, provided frank and open assessments on the relationships between the agencies and the MOA document. While not as warm an encounter as with the SFDA Commisioner Shao, Madam Qu and Commissioner von Eschenbach talked easily, sharing experiences and looking forward to on-going discussions between the technical teams as well as closer relationships between their agencies.

¶16. (SBU) The meeting with AQSIQ VW Wei over a short lunch still demonstrated that both the Commissioner and Wei were confidant and comfortable letting their staff (technical teams) work out the

details of the MOA language in the up-coming negotiations. Despite only meeting face-to-face once before, they were relaxed and comfortably talked about personal things like their home towns and professional experiences leading up to their current positions. They were at ease sharing the developing and improving collaboration between AQSIQ and FDA as they each reaffirmed to one another the benefits of increased product safety that would accrue for their citizens and their governments.

RANDT